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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,727	12/26/2001	Sukanta Banerjee	4364-4005	1379

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EXAMINER

YANG, NELSON C

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/034,727

Applicant(s)

BANERJEE ET AL.

Examiner

Nelson Yang

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 October 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 82-91 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 82-91 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/15/03, 12/22/03
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: IDS: 1/27/03, 10/18/04

S.O. 2

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's cancellation of claims 1-48 and addition of claims 82-91 is acknowledged and has been entered.
2. Claims 82-91 are currently pending.

### ***Election/Restrictions***

3. Since applicant has cancelled all claims being restricted, the restriction requirement is now moot, and has been withdrawn.

### ***Information Disclosure Statement***

4. The IDS filed on December 22, 2003 has not been considered as the references appear to be duplicates of the references of the IDS filed on December 15, 2003.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 82-91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. With respect to claim 82, it is unclear if the statement "a substantially planar assembly of beads wherein member beads encoded differently ..." is intended to be interpreted that the member beads are each encoded differently, or that if the beads are encoded differently. Further clarification of the limitation would be greatly appreciated.

Art Unit: 1641

8. The remaining claims are indefinite due to their dependence on an indefinite claim.

*Claim Rejections - 35 USC § 102*

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

10. Claims 82-86, 89, 91 are rejected under 35 U.S.C. 102(e) as being anticipated by Muller-Schulte [US 6,514,688].

With respect to claims 82, 83, Muller-Schulte teaches magnetic particles with a particle size in the range of 1-10  $\mu\text{m}$  (column 3, lines 58-65) suspended in a cross-linked polymer matrix (column 6, lines 45-55). Muller-Schulte further teach coupling one or more types of ligands to the surface of the particles, and labeling through coupling with antibodies for certain cell markers (column 9, lines 10-20). The encoding would be the physical characteristic of the different antibodies bound to the particles.

11. With respect to claim 84, the polymer is comprised of at least one emulsifier with semi-hydrophilic properties, i.e. which is soluble in both oil and water (column 4, lines 25-30).
12. With respect to claims 85-86, the ligands can be antibodies (column 9, lines 10-20).
13. With respect to claims 89, 91, Muller-Schulte teaches magnetic particles with a particle size in the range of 1-10 $\mu\text{m}$  (column 3, lines 58-65).

Art Unit: 1641

14. Claims 82-83, 85-87, 89 are rejected under 35 U.S.C. 102(b) as being anticipated by Shinoki et al [US 6,531,323].

With respect to claims 82, 83, Shinoki et al teach a non-fluid substance such as a gel (column 5, lines 25-30) for retaining labeling particles having anti-analytes bound thereto (column 5, lines 8-10). The particles may contain different antibodies (column 4, lines 23-25). The encoding would be the physical characteristic of the different antibodies bound to the particles.

15. With respect to claims 85, 86, Shinoki et al teach that the particles contain antibodies bound to the particle (column 4, lines 5-10).

16. With respect to claim 87, Shinoki et al teach a support (column 6, lines 44-56).

17. With respect to claim 89, the particle size is about 1 to 500 nm (column 4, lines 65-67).

18. Claims 82-86, 89, 91 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al [US 6,713,309].

With respect to claim 82, Anderson et al teach biochips comprising beads with different binding components comprising biological molecules (column 6, lines 15-25) contained in a gel within microtubes (column 6, lines 44-56), wherein the location determines what analyte will be bound to the binding component (column 5, lines 35-50) and detection is performed by changes in fluorescence or optical absorbance (column 10, lines 10-15). The microtubes are bonded into bundles, and thin sections of cut to form flat arrays (column 6, lines 55-67).

19. With respect to claim 83, the physical characteristic of the location of the beads and the binding component distinguishes beads from each other (column 5, lines 35-50).

Art Unit: 1641

20. With respect to claims 85-86, the binding components can include proteins, peptides, nucleic acids (column 5, lines 40-50).

21. With respect to claim 87, the biochips can comprise glass slides (column 29, lines 5-10)

***Claim Rejections - 35 USC § 103***

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

23. Claim 89 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al [US 6,713,309] in view of Bryan et al [US 6,458,547].

With respect to claim 82, Anderson et al teach biochips comprising beads with different binding components comprising biological molecules (column 6, lines 15-25) contained in a gel within microtubes (column 6, lines 44-56), wherein the location determines what analyte will be bound to the binding component (column 5, lines 35-50) and detection is performed by changes in fluorescence or optical absorbance (column 10, lines 10-15). The microtubes are bonded into bundles, and thin sections of cut to form flat arrays (column 6, lines 55-67). Anderson et al do not teach that the biochips comprise a silicon chip.

Bryan et al, however, teach the use of silicon chips (column 14, lines 14-21, 45-50), and further teach that the chip is adaptable for use in an array format for the detection and identification of agents in a biological sample with the device (column 5, lines 20-25), using circuits for integrating the output data signals and accumulating them, and further generating an

Art Unit: 1641

output device signal, in order to generate visible indicia related to the presence of the analytes (column 5, lines 45-55).

Therefore, it would have been obvious for the substrate to be a silicon chip in the device of Anderson et al, as suggested by Bryan et al, in order to adapt the device for use in the detection and identification of analytes and generation of visible indicia related to the presence of the analytes.

24. Claim 90 is rejected under 35 U.S.C. 103(a) as being unpatentable over Muller-Schulte [US 6,514,688] in view of Schulz et al [US 4,663,408].

Muller-Schulte teaches magnetic particles with a particle size in the range of 1-10  $\mu\text{m}$  (column 3, lines 58-65) suspended in a cross-linked polymer matrix (column 6, lines 45-55). Muller-Schulte further teach coupling one or more types of ligands to the surface of the particles, and labeling through coupling with antibodies for certain cell markers (column 9, lines 10-20). Muller-Schulte does not teach that the polymer comprises cross-linked alkyl acrylamide or hydroxylalkyl acrylate hydrogel.

Schulz et al, however, teach that long chain alkyl acrylamide enhance the viscosification efficiency of the copolymers they are in (column 1, lines 62-65).

Therefore, it would have been obvious in the invention of Muller-Schulte for the polymer to comprise alkyl acrylamide, as suggested by Schulz et al, in order to increase the viscosification efficiency of the polymer matrix.

25. Claim 90 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al [US 6,713,309] in view of Schulz et al [US 4,663,408].

With respect to claim 90, Anderson et al teach biochips comprising beads with different binding components comprising biological molecules (column 6, lines 15-25) contained in a gel within microtubes (column 6, lines 44-56), wherein the location determines what analyte will be bound to the binding component (column 5, lines 35-50). The microtubes are bonded into bundles, and thin sections of cut to form flat arrays (column 6, lines 55-67). Anderson et al do not teach that the polymer comprises cross-linked alkyl acrylamide or hydroxylalkyl acrylate hydrogel.

Schulz et al, however, teach that long chain alkyl acrylamide enhance the viscosification efficiency of the copolymers they are in (column 1, lines 62-65).

Therefore, it would have been obvious in the invention of Anderson et al for the polymer to comprise alkyl acrylamide, as suggested by Schulz et al, in order to increase the viscosification efficiency of the polymer matrix.

26. Claim 90 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shinoki et al [US 6,531,323] in view of Schulz et al [US 4,663,408].

With respect to claim 90, Shinoki et al teach a non-fluid substance such as a gel (column 5, lines 25-30) for retaining labeling particles having anti-analytes bound thereto (column 5, lines 8-10). The particles may contain different antibodies (column 4, lines 23-25). The encoding would be the physical characteristic of the different antibodies bound to the particles.

Schulz et al, however, teach that long chain alkyl acrylamide enhance the viscosification efficiency of the copolymers they are in (column 1, lines 62-65).



Therefore, it would have been obvious in the invention of Shinoki et al for the polymer to comprise alkyl acrylamide, as suggested by Schulz et al, in order to increase the viscosification efficiency of the polymer matrix.

### *Double Patenting*

27. Claims 82-91 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 53-67 of copending Application No. US 2003/0138842. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim beads embedded in a polymer.

28. With respect to claims 82-84, the copending application claims a single layer assembly of beads embedded in a hydrophilic polymeric matrix, wherein said beads have biomolecules attached to their surfaces and are further distinguishable by a unique chemical or physical characteristics (claim 53).

29. With respect to claims 85-86, the biomolecules can be proteins (claim 55), or receptors (claim 57).

30. With respect to claims 87-89, the assembly is located on a silicon chip (claim 58), with an average diameter of 0.5 to 100  $\mu\text{m}$  (claim 60).

31. With respect to claim 90, the polymer comprises cross linked alkylacrylamide or hydroxyalkylacrylate hydrogel (claim 60).

32. With respect to claim 91, the beads comprise magnetic beads (claim 62).

33. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### *Conclusion*

Art Unit: 1641


34. No claims are allowed.

35. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

36. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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06/20/05